Centers for Disease Control and Prevention (CDC)
National Center for Infectious Diseases (NCID)
Biostatistics and Information Management Branch

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Title: **CDC Program ELISA Installation Qualification Protocol**		
Location: Electronic Copy: ZIP disk\Numbered projects\0082\ELISA\PROTOCOLS Hard Copy: CDC Roybal Campus, Building 1, Room 4062 (Brian D. Plikaytis)		
Prepared by: Brian D. Plikaytis	QA Review: Name (typed): Initials and Date:	Approving Authority: Name (typed): Signature and Date

1.0 Purpose

The objective of this protocol is to confirm the proper acquisition and installation of the 32-bit version of the CDC Program ELISA Software system. This protocol will validate that the software is installed on the selected stand-alone computer system and/or network environment.

2.0 Approvals

2.1 Protocol Pre-Approval

Completion of the Protocol Pre-Test Approval signature block indicates that this Installation Qualification (IQ) protocol has been reviewed by the appropriate quality control authorities within the relevant departments to ensure that all defined procedures are accurate, complete, and consistent for the stated purpose, and that the software test execution may commence.

Department	Print Name	Signature	Date
System Owner/User			
QA Validation			

2.2 Protocol Post-Approval

Completion of the Protocol Post-Test Approval signature block indicates that this Installation Qualification (IQ) protocol has been reviewed by the appropriate quality control authorities within the relevant departments to ensure that all testing was executed as specified, all actual results are fully documented and attached, data sheets are completed, all deficiencies and deviations encountered are resolved, all acceptance criteria have been met, and that the validation of this system is considered complete.

Department	Print Name	Signature	Date
System Owner/User			
QA Validation			
Effective Date:			

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3.0 References

3.1 Pre-Qualification Documents

List each Pre-Qualification Document that applies and verify that the document was approved and is available. Record the current document number, including revision. Initial and date each entry.

Document Name	Document Number	Initial/Date

3.2 Standard Operating Procedures

List each Standard Operating Procedure (SOP) that applies and verify that the SOP is available. Record the current document number, including revision. Initial and date each entry.

SOP Name	SOP Number	Initial/Date

3.3 Study Specific Procedures

List each Study Specific Procedure (SSP) that applies and verify that the SSP is available. Record the current document number, including revision. Initial and date each entry.

SSP Name	SSP Number	Initial/Date

3.4 Manuals

List each used, verify that the manual is available and provide the current document number, including revision. Initial and date each entry.

Document Name	Document/Version Number	Initial/Date
CDC ELISA User's Manual		

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4.0 Computer Workstation Hardware Components

Procedure: Inspect and document the computer system attributes listed below. Initial and date each entry.

Item	Actual	Initials/Date
Computer system manufacturer		
Computer system model		
Computer system serial number		
Processor speed Note: 250MHz minimum		
Ram size available Note: 64 MB minimum		
Hard disk available Note: 10 MB minimum		

5.0 Computer System Server Hardware Components

Procedure: Inspect and document the computer system attributes listed below. Initial and date each entry.

Item	Actual	Initials/Date
Computer system manufacturer		
Computer system model		
Computer system serial number		
Processor speed Note: 250MHz minimum		
Ram size available Note: 64 MB minimum		
Hard disk available Note: 10 MB minimum		

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6.0   Computer Workstation Software Summary

Procedure: For each section, list the information listed. Initial and date each entry. Note: CDC ELISA is not a certified network application but it has been tested and is running successfully in a network environment at the CDC.

Item	Actual	Initials/Date
Custom application name		
Version number		
Distributor	Centers for Disease Control and Prevention	
Master electronic copy location		
Working electronic copy location		

7.0   Computer System Server Software Summary

Procedure: For each section, list the information listed. Initial and date each entry. Note: CDC ELISA is not a certified network application but it has been tested and is running successfully in a network environment at the CDC.

Item	Actual	Initials/Date
Custom application name		
Version number		
Distributor	Centers for Disease Control and Prevention	
Master electronic copy location		
Working electronic copy location		

8.0   System Overview

CDC Program ELISA abstracts, processes and analyzes bioassay data obtained from 96-well microtiter plates. The software interprets data files exported from various ELISA readers as well as a generic file format created by the user. The software estimates and plots standard curves and calculates antibody concentrations for sample sera. Results may be stored for subsequent analysis in external statistical analysis software packages. The software operates under a Windows® 32-bit environment (e.g., Windows 2000, NT, etc.). It may be installed on a PC stand-alone computer or in a network environment.

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9.0   Software and Documentation Acquisition/Download

For each Required Action, detail the observed result in the Actual Observations column and circle YES or NO in the Criteria Met column to indicate the Actual Observation matched the Expected Result. Initial and date each entry.

Required Action	Expected Result	Actual Observation	Criteria Met	Initials/Date
Download software and documentation from: http://www.cdc.gov/ncird/software /elisa/download.html	Fill in web registration form.		YES/NO	
Click on 'Send Information and Download Now'	Link to web site thanking you for sharing information with CDC.		YES/NO	
Click on 'Download ELISA Software Now'	Link to software download page.		YES/NO	
Right-click on 'ELISA Manual.pdf'	Drop-down menu appears.		YES/NO	
Click on 'Save Target As...' or 'Save Link As…'	File save dialog box appears with ELISA_Manual.pdf in the File name: box. Adobe Acrobat Document should appear in the Save as type: box.		YES/NO	
Select subdirectory for file storage in Save in: box. Click on the Save box.	File download progress box appears during download process. Disappears when file download complete.		YES/NO	
Use Windows Explorer to confirm 'ELISA Manual.pdf' file resides in the correct subdirectory.	'ELISA Manual.pdf' does exist in the correct subdirectory.		YES/NO	
Return to ELISA for Windows download web page	Web page displayed.		YES/NO	
Right-click on 'ELISA_32.zip'	Drop-down menu appears.		YES/NO	
Click on 'Save Target As...' or 'Save Link As…'	File save dialog box appears with ELISA_32.zip in the File name: box. WinZip File should appear in the Save as type: box.		YES/NO	
Select subdirectory for file storage in Save in: box. Click on the Save box.	File download progress box appears during download process. Disappears when file download complete.		YES/NO	
Use Windows Explorer to confirm 'ELISA_32.zip' file resides in the correct subdirectory.	'ELISA_32.zip does exist in the correct subdirectory.		YES/NO	

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10.0   Software Installation

The software may be installed on a workstation PC or on a network server. When the ELISA_32 file is unzipped, the files will be extracted to the subdirectory \ELISA_32 beneath the directory where the zip file is located. Seven additional subdirectories are created beneath \ELISA_32 which contains another copy of the user's guide or manual, test data and analysis files used to check program file manipulations, result files to compare with files resulting from program execution during the validation stage, the installation qualification protocol, the operational qualification protocol, and a validation report.

10.1   Workstation Installation

Required Action	Expected Result	Actual Observation	Criteria Met	Initials/Date
Use Windows Explorer to locate the file ELISA_32.zip.	The file ELISA_32.zip is found and the file is displayed in the Windows Explorer window.		YES/NO	
Extract all files using any unzip utility (e.g., WinZip).	The subdirectory \ELISA_32 is created under the directory where the ELISA_32.zip file is located. Subdirectories \Documentation, \Installation Qualification Protocol, \Operational Qualification Protocol, \Result Files, \Test Data, and \Validation Report are created under subdirectory \ELISA_32.		YES/NO	
Double-click on the file SETUP.EXE within the ELISA_32 subdirectory.	The ELISA Setup dialog appears.		YES/NO	
Select OK in the 'Welcome to the Elisa installation program' box	Begin installation box appears. The directory 'C:\Program Files\Elisa\' is suggested as the directory for software installation.		YES/NO	
If desired, change installation directory by clicking on Change Directory.	Directory setup screen appears.		YES/NO	
When installation directory is selected, click on the icon to the left of the instruction 'Click this button to install Elisa software to the specified destination directory.'	Software is installed. The message 'Elisa Setup was completed successfully' should appear.		YES/NO	
Select 'OK' to close setup window and finish installation.	Computer display returns to the original Windows Explorer screen.		YES/NO	

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Required Action	Expected Result	Actual Observation	Criteria Met	Initials/Date
Click Windows 'Start' menu button.	Start menu appears.		YES/NO	
Select the Programs folder.	Programs installed on computer appear.		YES/NO	
Locate CDC ELISA and select it.	ELISA opening screen appears.		YES/NO	
Confirm the version and date correspond with that cited on the ELISA download webpage: http://www.cdc.gov/ncird/software/elisa/download.html	The version and date agree.		YES/NO	

10.2   Network Installation

CDC ELISA is not a certified network application but it has been tested and is running successfully in a network environment at the CDC. The following instructions detail how to install CDC ELISA on a network but the program authors offer no guarantee that it will work in all environments. These instructions are offered as a guide to assist those users who wish to investigate if the software will work on networks in their facilities. In all likelihood, a person with network administrative privileges will be required to perform these steps. The initial installation process is the same as that for a workstation installation described in section 5.1. Once this is done, program files are transferred to the desired network drive and a shortcut created on the network workstation that will point to the executable file on the network. During the installation process some common Windows system and Visual Basic files are copied to the workstation's Windows subdirectories and an entry is made in the registry. These operations are detailed in the file ST5UNST.LOG located in the directory where the program was installed (the same directory containing the ELISA_32.EXE file). Once the network installation is complete, as described in this section, secondary workstations may create a shortcut pointing to the program on the network (also described in this section). This is the current practice within the laboratories that use this program at the CDC. However, CDC policies dictate a high degree of standardization among computers within the agency which facilitates this process. In other environments with computers that may run different levels, versions, or flavors of Windows, the secondary workstations may have difficulties running the program off the network. If this is the case, it is possible these workstations lack some of the files which were copied during the program installation process on the primary workstation. This may be surmounted by doing a 'client' installation on the secondary workstations. In this case, the installation is performed exactly as described in section 5.1. After the installation is complete, the ELISA executable file on the workstation hard drive is ignored and an icon created that will point to the network copy of the program.

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Required Action	Expected Result	Actual Observation	Criteria Met	Initials/Date
Use Windows Explorer to locate the file ELISA_32.zip.	The file ELISA_32.zip is found and the file is displayed in the Windows Explorer window.		YES/NO	
Extract all files using any unzip utility (e.g., WinZip). The target directory should reside on a network workstation.	The subdirectory \ELISA_32 is created under the network workstation directory where the ELISA_32.zip file is located. Subdirectories \Documentation, \Installation Qualification Protocol, \Operational Qualification Protocol, \Result Files, \Test Data, and \Validation Report are created under subdirectory \ELISA_32.		YES/NO	
Double-click on the file SETUP.EXE within the ELISA_32 subdirectory.	The ELISA Setup dialog appears.		YES/NO	
Select OK in the 'Welcome to the Elisa installation program' box	Begin installation box appears. The directory 'C:\Program Files\Elisa\' is suggested as the directory for software installation.		YES/NO	
If desired, change network workstation installation directory by clicking on Change Directory.	Directory setup screen appears. If the directory is changed, ensure it remains on the network workstation and not a network drive or subdirectory.		YES/NO	
When network workstation installation directory is selected, click on the icon to the left of the instruction 'Click this button to install Elisa software to the specified destination directory.'	Software is installed. The message 'Elisa Setup was completed successfully' should appear.		YES/NO	
Select 'OK' to close setup window and finish installation.	Computer display returns to the original Windows Explorer screen.		YES/NO	
Locate the installation subdirectory (default is directory C:\Program Files\Elisa\)	Directory is found.		YES/NO	
Copy the entire contents of this subdirectory to a network directory.	Files are copied.		YES/NO	

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Required Action	Expected Result	Actual Observation	Criteria Met	Initials/Date
Create a shortcut to the ELISA_32.EXE program located on the network directory – right-click on the Windows wallpaper.	Pull-down menu appears.		YES/NO	
Select 'New'.	Second pull-down menu appears.		YES/NO	
Select 'Shortcut'	Shortcut creation dialog box appears requesting the location of the item.		YES/NO	
Select 'Browse'.	File location dialog appears.		YES/NO	
Locate the network directory where the program files reside. Highlight 'elisa_32.exe. Select 'OK'.	Directory and program name appear in the 'location of the item' box.		YES/NO	
Select 'Next'.	Dialog box requesting a name for the item appears.		YES/NO	
Enter a name for the shortcut (e.g., ELISA_32). Select 'Finish'.	Shortcut is created on desktop.		YES/NO	
If the shortcut creation dialog reappears requesting the location of the item, select 'Cancel'.	Shortcut dialog box disappears. Icon for ELISA_32 appears on wallpaper.		YES/NO	
Double-click ELISA_32 icon.	ELISA opening screen appears.		YES/NO	
Confirm the version and date correspond with that cited on the ELISA download webpage: http://www.cdc.gov/ncird/software/elisa/download.html	The version and date agree.		YES/NO	
Create shortcut on secondary workstation.	Shortcut is created.		YES/NO	
Double-click ELISA_32 icon.	ELISA opening screen appears.		YES/NO	
If software does not operate properly, perform a 'client' installation on secondary workstation following instructions in section 5.1.	Installation completes normally.		YES/NO	
Retry executing network version of the software by double-clicking on the ELISA software shortcut previously created.	ELISA opening screen appears.		YES/NO	

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11.0   Problem resolutions

If any problems occur during the installation process please:

1. Double-check installation procedure.
2. Check operating system to verify that they are in accordance with the recommendations in Section 3.0.
3. Repeat installation procedure.
4. If problem persists, contact Brian Plikaytis at the CDC for additional assistance at (404) 639-4711.